

## REMARKS / ARGUMENTS

This Amendment is submitted in response to the final office action dated November 12, 2003, in connection with the above-identified application. A Notice of Appeal is being filed concurrently herewith.

Claims 1-27 are currently pending. Applicant respectfully requests that Claims 1, 2, 3 and 13 be amended. Applicant also respectfully requests the Claim 12 be cancelled without prejudice. Applicant reserves the right to prosecute this Claim at a later date. Thus, Claims 1-11 and 13-27 are currently pending.

### A. Rejections Under 35 U.S.C. 112, Second Paragraph

The Examiner has rejected Claims 1-11 under 35 U.S.C. 112, Second Paragraph as being based on a disclosure which is not enabling. Specifically, the Office Action states, "the 'active substance' is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure [sic]. Step (a) (2) does not require the present [sic] of active substance."

Applicant respectfully disagrees with the Examiner's assertion. The language of Claim 1 relates to the following scenarios:

- (I) all of the active is powdered/granulated [step (a)(1)] and dispensed in an auxiliary solvent [(b)(1)];
- (II) part of the active is powdered/granulated [step (a)(1)] and dispensed in a solution/dispersion of the remainder of the active in an auxiliary solvent [(b)(2)];
- (III) the other pharmaceutical ingredients are powdered/granulated [(a)(2)] and dispensed in solution /dispersion of total of active in auxiliary solvent [(b)(2)].

The preamble in Claim 1 states the requirement of an active substance, in order for a skilled artisan to practice Claim 1 when starting, for example, with "other pharmaceutical ingredients", she has to follow step [(a)(2)] with step [(b)(2)] not [(b)(1)] to add in the active substance. Thus, Applicant disagrees with the Examiner's assertion that step [(a)(2)] does not require an active substance.

The Examiner has rejected Claims 1-11 under 35 U.S.C. 112, Second Paragraph as being based indefinite. Specifically, Claim 1 is rejected because of insufficient antecedent basis for the term "the other ingredients." Applicant has amended this term to read as "the other pharmaceutical ingredients" which does have antecedent basis.

Claim 1 is rejected in the use of step [(a)(2)]. Applicant respectfully submits that the active substance is ultimately present in the invention regardless of whether a skilled artisan begins with step [(a)(1)] or step [(a)(2)]. Applicant respectfully refers the Examiner to the aforementioned remarks.

It is respectfully submitted that this rejection is overcome and should be withdrawn.

### **B. Rejections Under 35 U.S.C. 102**

Claims 12-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/38679 to Humbert-Droz et al. (hereinafter "*Humbert*"). The Examiner states that *Humbert* teaches fast disintegrating oral dosage forms comprising active agent, filler, binding agent (disintegration agent), and talc as lubricant. Applicant respectfully notes the cancellation without prejudice of Claim 12. Applicant respectfully submits that *Humbert* fails to include the disintegration agents disclosed in Claim 13.

The CAFC has repeatedly stated that "it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 2131 USPQ 81 (Fed. Cir. 1986). In the present case, this axiom is not met.

Applicant submits that binding agents and disintegration agents have different purposes and are not the same compounds, thus, not being interchangeable. The purpose for which these ingredients are included differentiates these agents. A binder is an agent that holds the ingredients together as a solid dosage form (e.g., a tablet). In contrast, a disintegration agent helps in the rapid disintegration of the tablet when the tablet is administered.

Claim 13 has been amended such that the disintegration agent is "selected from the group consisting of croscarmellose Na, sodium glycolates of starches, cross-linked poly-N-vinyl-2-pyrrolidones, polymethylmethacrylates, soy polysaccharides and synthetic resins." Support for "soy polysaccharides" can be found in the recitation of EMCOSoy on page 11 of the Specification. EMCOSoy from JRS Pharma LP is soy polysaccharides (a copy of literature disclosing EMCOSoy is submitted herewith).

In view of the fact that the *Humbert* fails to teach each and every element of the claimed invention, it is respectfully submitted that Claim 13 and its dependent claims are in condition for allowance. Applicant respectfully requests that this rejection be withdrawn.

### **C. Rejections under 35 U.S.C. 103**

Claims 1-27 are rejected under 35 U.S.C. 103 as being unpatentable over *Humbert*.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claimed limitations. See, *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

With respect to the method claims, the Examiner stated that *Humbert* is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate, but the extra step does not impart patentability over the prior art. The Examiner states there is no criticality seen in this particular step. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness because *Humbert* is indeed silent regarding the compacting of a suitable amount of the prepared powder or granulate.

Applicants respectfully submits that the present invention not only accomplishes a rapidly dissolving oral dosage form, but also a rapidly dissolving oral dosage form that overcomes many problems associated with drying suspensions that are filled in blister packs. For example, page 2 of the Specification states these problems that are overcome by the specific manufacturing process of the present invention which includes the unique compacting step:

- (a) assuring that the dosage forms always have a uniform content of the active ingredient(s);
- (b) assuring that the dosage forms always have a uniform table weight (e.g. dose weights accurate within 2-3%);
- (c) avoiding a time-consuming process for removing high quantities of solvent;
- (d) allowing easy upscaling of the process developed the laboratory; and
- (e) avoiding moisture uptake during storage."

These aforementioned clear and unexpected advantages are not taught or suggested by *Humbert*.

Thus, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, it is respectfully submitted that this rejection is overcome and should be withdrawn.

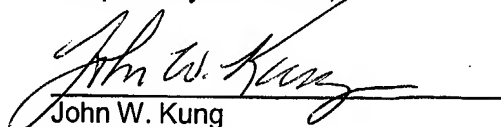
#### **D. Obviousness Type Double Patenting Rejection**

Claims 12-26 are rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,083,531 the ("531 Patent"). For clarification purposes, Applicant notes that *Humbert* is the PCT priority document of the '531 Patent.

As discussed before, the composition claims of the present invention are significantly different from that of *Humbert*. The disintegration agents disclosed in Claim 13, *i.e.*, croscarmellose Na, sodium glycolates of starches, cross-linked poly-N-vinyl-2-pyrrolidones, polymethylmethacrylates, soy polysaccharides and synthetic resins, are distinctly and chemically distinct from the binding agents disclosed in *Humbert*. Accordingly, the claims of the present invention are not obvious since the compositions are not identical.

Thus, it is respectfully submitted that this rejection be withdrawn.

Respectfully submitted,

  
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